



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

IN RE: ZANTAC (RANITIDINE)
PRODUCTS LIABILITY) GENERAL ZANTAC
) LITIGATION
) CIVIL ACTION NO.:
) N22C-09-101 ZAN
)

[JOINT PROPOSED] CASE MANAGEMENT ORDER NO. 1

This Case Management Order (“CMO”) was jointly proposed by the undersigned Plaintiffs’ counsel and counsel for certain Defendants, including GlaxoSmithKline LLC (“GSK”), Pfizer Inc. (“Pfizer”), Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim U.S.A. Corporation (the “BI Defendants” or “BI”), Sanofi US Services Inc., Sanofi-Aventis U.S. LLC, and Chattem Inc. (“the Sanofi Defendants” or “Sanofi”) (collectively, “the Brand Defendants,” and together with Plaintiffs’ counsel, “the Agreeing Parties”). This CMO will apply to all personal injury and/or wrongful death cases alleging the use of prescription or over-the-counter Zantac (or any ranitidine-containing product) currently pending in the Superior Court of the State of Delaware, as well as any future cases that are filed in, transferred to, or otherwise pending in this Court (“the Zantac Litigation”).

In light of the number of cases and parties involved, the Agreeing Parties have stipulated and the Court has determined that special case management

measures will promote efficient resolution of these actions. Toward that end, the Zantac Litigation shall proceed initially on two simultaneous tracks, with: (1) one track designed to obtain a threshold ruling on the admissibility of expert evidence relating to general causation (*i.e.*, whether Zantac can cause certain cancers) applicable to all matters in the Zantac Litigation (“the General Causation Track” and “the General Causation Ruling”); and (2) a second track designed to organize and facilitate the parties’ and Court’s analysis of the docket for purposes of identifying representative cases for bellwether discovery and trials (“the Bellwether Track”).

Accordingly, the following deadlines are hereby ORDERED:

1. **General Matters Governing the Zantac Litigation.**

a. **Appointment of Lead and Liaison Counsel:**

- i. The Court hereby appoints Jennifer A. Moore, Raeann Warner, R. Brent Wisner, and Justin Parafinczuk as Plaintiffs’ Co-Lead National Counsel. Plaintiffs’ Co-Lead National Counsel’s duties shall include to generally coordinate and oversee all activities for all plaintiffs. Plaintiffs’ Co-Lead Counsel have the authority and duty to present to the Court and opposing parties the position of Plaintiffs on all matters arising during pretrial

proceedings; propose agenda items for case management conferences and appear at case management conferences and hearings; draft case management orders for the orderly and efficient litigation of this action; initiate and coordinate all pretrial discovery on behalf of Plaintiffs including developing and proposing to the Court schedules for discovery; submit and argue all motions presented to the Court on behalf of Plaintiffs and oppose motions submitted by Defendants or other parties; enter into stipulations with opposing counsel necessary for advancement and conduct of this litigation; act as spokesperson for Plaintiffs at case management conferences and pretrial proceedings; and perform any other task necessary to accomplish efficient and effective coordination of pretrial proceedings on behalf of all Plaintiffs.

- ii. The Court hereby appoints Bernard Conaway, Stephen Morrow, Joseph Rhoades, and Raeann Warner as Plaintiffs' Lead Delaware Counsel.

- iii. The Court hereby appoints the Brand Defendants' Lead Delaware Counsel to be Colleen Shields for GSK; Daniel J. Brown for Pfizer; Joseph S. Naylor for BI; and Nancy Shane Rappaport for Sanofi.
 - iv. The Court hereby appoints the Brand Defendants' Lead National Counsel to be Mark S. Cheffo for GSK; Joseph G. Petrosinelli for Pfizer; Andrew T. Bayman for BI; and Loren H. Brown for Sanofi.
 - v. Other Defendants' counsel who appear in the Zantac Litigation shall identify their lead Delaware counsel (and lead national counsel, if any) when those counsel enter their appearances.
- b. Creation of Master Docket:
- i. The Clerk of the Court is directed to create a Master Docket for all the cases coordinated within the Zantac Litigation.
 - ii. All pleadings, orders, motions, and other documents that are generally applicable to all the matters coordinated in the Zantac Litigation shall include the caption *In re Zantac (Ranitidine) Litigation* and shall be filed and

docketed only in the Master Docket bearing the case number reflected above.

- iii. Documents intended to apply only to particular cases will indicate in their caption the individual case number(s) and case name(s) to which they apply and be filed only in the individual case(s), not the Master Docket.

c. Pleadings:

- i. Defendants are hereby relieved of their obligation to file answers or otherwise respond to Complaints, including those currently on file, unless and until a plaintiff is selected for bellwether discovery and files an individual Complaint pursuant to paragraph **Error! Reference source not found.**, or other plaintiffs file individual Complaints pursuant to paragraph 5.b. All affirmative defenses and potential cross-claims (if any) between Defendants shall be deemed to be preserved.
- ii. Defendants shall file an Entry of Appearance on the Master Docket no later than April 28, 2023, or 30 days of being served, whichever is later. Each Defendant only need file one Entry of Appearance. Upon filing an Entry

of Appearance on the Master Docket on behalf of a Defendant, all Complaints filed or to be filed in the Zantac Litigation naming that Defendant shall be deemed answered and generally denied by that Defendant.

d. Dismissals:

- i. Any plaintiff who wishes to dismiss her or his case, including via the Docket Spreadsheet process set forth below, may do so without prejudice; provided, however, that any such voluntary dismissal without prejudice shall be subject to the condition that if the plaintiff refiles any claim involving personal injury and/or wrongful death relating to ranitidine, she or he may do so only in this Court.
- ii. This provision shall be without prejudice to the Agreeing Parties later agreeing, or the Court later ordering, that dismissals of plaintiffs who are randomly selected for the Bellwether Track who choose to dismiss their Complaints shall be with prejudice.

2. Individual Plaintiff Information.

- a. Docket Spreadsheet: By April 28, 2023, Plaintiffs' Counsel shall provide to Defendants an Excel spreadsheet listing key data for every plaintiff with a filed case in the Zantac Litigation as of that date ("the Docket Spreadsheet"), including: (1) name; (2) plaintiff's law firm; (3) case number; (4) state of residence; (5) product used (OTC and/or prescription; branded and/or generic); (6) time period(s) of use; (7) defendants against whom claims are asserted; (8) type of cancer(s) alleged; (9) date of diagnosis; (10) date of death (if applicable); and (11) personal representative name (if applicable). The parties may agree to establish an online portal for receipt of the Docket Spreadsheets to be submitted by individual plaintiff's firms and overseen by Plaintiffs' Co-Lead Counsel.
- b. Deficiencies in Docket Spreadsheet: Defendants shall have 28 days (until Friday, May 26, 2023) to notify Plaintiffs' Co-Lead Counsel and the individual Plaintiff's firm of any alleged deficiency on the Docket Spreadsheet that is apparent from the face of the spreadsheet. Plaintiffs shall have 28 days (until Friday, June 23, 2023) to cure any such alleged deficiency. If

the parties cannot reach agreement on whether an entry is deficient, they shall meet and confer to resolve the dispute. If any information a plaintiff provides in the Docket Spreadsheet later is uncovered to be inaccurate, and that plaintiff is chosen for the Bellwether Track (as defined below), the parties shall meet and confer regarding whether and how the plaintiff should be removed and/or replaced from the Bellwether Track.

- c. Effect of Omission of Plaintiff from Docket Spreadsheet: All plaintiffs not included on the Docket Spreadsheet will have their claims dismissed without prejudice, subject to the refiling limitation in paragraph 1.d.i. and the meet and confer process below. When providing the Docket Spreadsheet to Defendants, Plaintiffs' Counsel shall list which plaintiffs (if any) have not provided the required information and thus are subject to having their claims dismissed without prejudice. Within 28 days thereafter, the parties shall submit to the Court stipulations of dismissal without prejudice for each such plaintiff who has not cured following a meet and confer process.

- d. Effect of Omission of Defendant from Docket Spreadsheet:
Claims against any Defendant not specifically identified in the Docket Spreadsheet entry for a particular plaintiff will be deemed dismissed without prejudice from the relevant complaint as to each such plaintiff, subject to the refiling limitation in paragraph 1.d.i.
- e. Later-Filed Plaintiffs. If any plaintiff files a complaint in the Zantac Litigation after April 28, 2023, that plaintiff shall not be eligible for selection for the Bellwether Track discussed below. Such plaintiffs will be required to provide the information described in paragraph 2.a at a later date, to be agreed by the parties or set by the Court.

3. **General Causation Track Deadlines.**

- a. On or before March 24, 2023, Plaintiffs shall disclose the cancer types for which they will proffer general causation experts (“the Delaware Cancers”).
- b. On or before July 17, 2023, Plaintiffs shall serve expert reports, signed by the expert, on the issue of general causation for the Delaware Cancers (“Plaintiffs’ Initial Experts”), and identify two available dates for deposition per expert.

- c. On or before August 21, 2023, Defendants shall serve expert reports, signed by the expert, on the issue of general causation for the Delaware Cancers, and identify two available dates for deposition per expert.
- d. On or before September 18, 2023, Plaintiffs shall serve any rebuttal expert reports, signed by the expert, on the issue of general causation for the Delaware Cancers (“Plaintiffs’ Rebuttal Experts”), and identify two available dates for depositions per expert. Rebuttal expert reports shall be limited to rebutting issues first introduced in Defendants’ Experts’ reports.
- e. On or before September 25, 2023, Defendants shall complete depositions of Plaintiffs’ Initial Experts. On or before October 9, 2023, Defendants shall complete depositions of Plaintiffs’ Rebuttal Experts. If Plaintiffs submit a rebuttal expert report from one of their Initial Experts, then that Initial Expert will be deposed between October 2 and October 9, 2023, subject to the expert’s availability.
- f. On or before October 25, 2023, Plaintiffs shall complete depositions of Defendants’ general causation experts.

- g. On or before November 1, 2023, the parties shall file *Daubert* motions relating to general causation experts. The parties shall meet and confer regarding the page limits and structure of briefing and shall submit a proposed case management order sufficiently in advance of this date to resolve any disputes before this deadline.
- h. On or before December 6, 2023, the parties shall file oppositions to *Daubert* motions relating to general causation experts.
- i. On or before December 22, 2023, the parties shall file reply briefs in support of their *Daubert* motions relating to general causation experts.
- j. The parties jointly request that the Court set a hearing on the parties' *Daubert* motions in between January 15 and January 31, 2024. The parties shall meet and confer regarding a proposed structure and length of that hearing and submit a proposed order on that subject (with either agreed or competing proposals) by November 15, 2023.

4. **Bellwether Track Deadlines.**

- a. The following provisions set forth a process for the parties to randomly select a pool of plaintiffs who will provide initial

written discovery and documents (“the Randomly Selected Plaintiffs”), from whom the parties will select a subset of plaintiffs for a limited number of fact depositions (“the Bellwether Discovery Plaintiffs”), from whom the parties will select a subset of plaintiffs for additional fact discovery, expert discovery, pretrial motions, and trial (“Bellwether Trial Plaintiffs”).

- b. On or before April 28, 2023, the Parties shall reach agreement on: (1) the content of a Plaintiff Profile Form (which will include, among other things, a list of health care providers) (“PPF”); (2) the content of authorizations for the collection of medical, employment, insurance, and Social Security records (“plaintiff-related records”); (3) a process for electronic service of PPFs and plaintiff-related records; and (4) a process for identifying and resolving any deficiencies in the PPFs and plaintiff-related records.
- c. On or before Monday, June 5, 2023, for each of the Delaware Cancers, the parties shall randomly select (using an agreed-upon randomization tool) a specific number of plaintiffs from among the group of plaintiffs that alleges such cancer as their

injury (“the Randomly Selected Plaintiffs”). The parties shall reach agreement before this date on the specific number of plaintiffs to be selected for each Delaware Cancer, and any plaintiffs who will be excluded from selection based on the information provided in the Docket Spreadsheet or otherwise. If a plaintiff is selected but has a deficiency in his or her Docket Spreadsheet submission, that plaintiff will have until June 23, 2023 to cure such deficiency; if the deficiency is not cured by that date, then the plaintiff will be removed from the pool and be replaced by a new plaintiff who is randomly selected.

- d. On or before Friday, May 26, 2023, the parties shall reach agreement on a schedule and process for fact discovery relating to the Randomly Selected Plaintiffs. That schedule and process shall include, at minimum, the following elements:
 - i. On or before September 1, 2023, each Randomly Selected Plaintiff shall provide a PPF and completed and executed authorizations for Defendants to collect records. Defendants may commence records collection immediately. In exchange for Plaintiffs voluntarily signing records authorizations, Defendants shall provide

electronic access to any obtained records. The cost for collection of the records associated with each Plaintiff will be borne by the Defendants for all employment, insurance, and Social Security records and for medical providers so long as identified by the Plaintiff in his or her PPF. For any medical providers not identified by the Plaintiff in his or her PPF, the parties will split the cost of collection evenly only if Plaintiff wishes to access the records; if Plaintiff does not wish to access the records, but Defendants depose the person who provided the records, then Defendants will provide Plaintiff access to the records at no cost to Plaintiff.

- ii. After the Randomly Selected Plaintiffs have provided PPFs and records, and after the parties have had sufficient time to analyze those documents, each side will select between 5 and 10 of the Randomly Selected Plaintiffs for each Delaware Cancer (*i.e.*, between 10 and 20 of the Randomly Selected Plaintiffs total for each Delaware Cancer, with the precise numbers to be agreed upon by the parties by May 26, 2023). Each side will be

able to strike two of the other side's selections for each of the Delaware Cancers. The parties will meet and confer to agree upon the dates for selections and strikes.

- e. The plaintiffs who are selected and not stricken ("the Bellwether Discovery Plaintiffs") will be the subject of a limited number of fact depositions of plaintiffs and their health care providers. By May 26, 2023, the parties shall reach agreement on the number of fact depositions relating to each Bellwether Discovery Plaintiff.
 - i. Such depositions may commence 30 days after the Court's General Causation Ruling.
 - ii. Each Bellwether Discovery Plaintiff must be severed from any multi-plaintiff Complaint and file an individual Complaint within 60 days after the Court's General Causation Ruling. Such individual Complaint will be deemed to relate back to the date of the filing of the original multi-plaintiff Complaint and can be served upon Defendants through electronic service as previously agreed upon by the parties.

- iii. Each named Defendant must file an answer to each individual Complaint filed by a Bellwether Discovery Plaintiff within 30 days of the filing (*i.e.*, within 90 days after the Court's General Causation Ruling). In answering, Defendants' right to file motions to dismiss or for summary judgment on the Bellwether Discovery Plaintiffs' Complaints, including on preemption, innovator liability, and all other grounds, shall be preserved.
- iv. Such depositions must conclude 120 days after the Court's General Causation Ruling (*i.e.*, the parties will have 90 days to complete the limited number of fact depositions for the Bellwether Discovery Plaintiffs).
- f. Within 30 days after the Court's General Causation Ruling, the parties will meet and confer to attempt to reach agreement on a schedule and process for narrowing the Bellwether Discovery Plaintiffs to a smaller number of plaintiffs within each remaining Delaware Cancer for additional fact discovery, expert discovery, summary judgment and other motions, and trial. Absent

agreement, the parties will submit competing proposals to the Court.

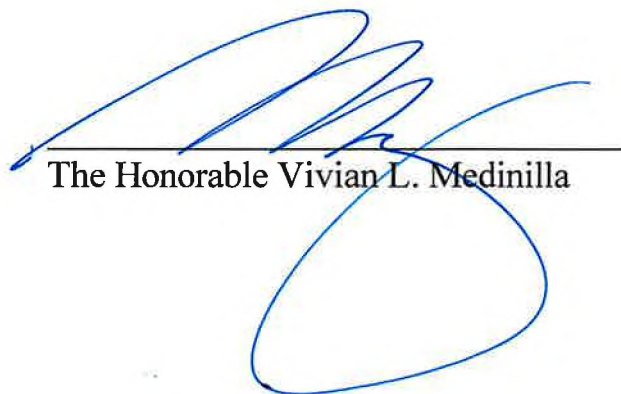
5. **Severance of Complaints.**

- a. A number of Complaints filed in the Zantac Litigation allege claims on behalf of multiple plaintiffs. Defendants' right to move under Delaware Superior Court Civil Rule 20 to sever the claims of multiple plaintiffs that are asserted in one Complaint is preserved, and will be addressed as described below.
- b. If Defendants' *Daubert* motions relating to general causation are denied as to any Delaware Cancers, then all plaintiffs in the Zantac Litigation alleging those cancers must be severed from multi-plaintiff Complaints and file their own individual Complaints, paying the requisite filing fee to the Clerk's Office. Those plaintiffs shall have until the date of the first bellwether trial, which will be set by the Court pursuant to paragraph 4.f, to sever their claims and file individual Complaints. Such individual Complaint will be deemed to relate back to the date of the filing of the original multi-plaintiff Complaint and can be served upon Defendants through electronic service as previously agreed upon by the parties. Any plaintiff who does

not file an individual Complaint as required under this paragraph shall have their claims dismissed without prejudice. Nothing in this paragraph shall affect the obligation of Bellwether Discovery Plaintiffs to file individual Complaints by the deadline in paragraph 4.e.ii.

- c. If Defendants' *Daubert* motions relating to general causation are granted as to any Delaware Cancers, such that summary judgment is granted as to all claims alleging those cancers, then plaintiffs in the Zantac Litigation alleging those cancers will not need to be severed from multi-plaintiff complaints. Those plaintiffs' claims will be dismissed with prejudice, so that those plaintiffs may appeal the Court's General Causation Ruling, if desired.

Date: March 23, 2023



The Honorable Vivian L. Medinilla